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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,073	06/27/2003	Michael D. Schneider	HO-P02514US2	1078

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/609,073	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) (B) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.0.D

DETAILED ACTION

Claims 1-35 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10 and 24-26, drawn to a method of treating a subject suffering from a cardiovascular disease or a method of treating heart failure comprising the administration of an effective amount of a composition to modulate cyclin dependent kinase 9 (Cdk9) activity or a method of modulating a decrease in cardiac muscle contractile strength, classified in class 514, subclass 320, for example.

II. Claims 11-23 and 27, drawn to a method of modulating myocyte enlargement in a subject at risk for cardiac hypertrophy or a method of modulating cardiac hypertrophy comprising the administration of an effective amount of a composition to modulate cyclin dependent kinase 9 activity or a method of treating a subject at risk for ventricular dysfunction associated with cardiac hypertrophy comprising the administration of an effective amount of a composition to modulate cyclin dependent kinase 9 activity, classified in class 514, subclass 320, for example.

III. Claims 28-34, drawn to a method of screening for a modulator of cyclin-dependent kinase 9 activity comprising obtaining Cdk9, contacting the Cdk9 with a candidate substance and assaying for Cdk9 activity, classified in class 435, subclasses 7.4 or 7.92, for example.

The inventions are distinct, each from the other, because of the following reasons:

Inventions I through III are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of Invention I (i.e., treating a subject suffering from heart failure) is distinct from the therapeutic objective of Invention II (i.e., modulating myocyte enlargement in a subject at risk for cardiac hypertrophy or modulating cardiac hypertrophy or treating ventricular dysfunction associated with cardiac hypertrophy), which is distinct from the therapeutic objective of Invention III (i.e., screening for a modulator of cyclin-dependent kinase 9 activity).

Regarding Inventions I and II, the treatment of either one of the Inventions of I or II would not necessarily result in the treatment of the other invention. The patient populations in which each method would be practiced are distinctly different (i.e., patients suffering from heart failure or patients suffering from cardiac hypertrophy), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing heart failure and those experiencing cardiac hypertrophy, the therapeutic objectives, endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with heart failure would necessarily be independent and distinct from that required for the treatment of patients with cardiac hypertrophy, due to the differences

in etiology of the disease and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of either I or II without practicing the invention of II or I, respectively. Thus, Inventions I and II are unrelated and considered independent and patentably distinct from one another.

Inventions I and II and Invention III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (See MPEP § 806.04, MPEP § 808.01). In the instant case, the inventive methods of Groups I-II and III are considered unrelated because the process steps involved in each invention are unique to the method and are distinctly different from the process steps of the other method, such that a search in the patent or non-patent literature for one of the methods would not result in a complete or comprehensive search of the other method. Furthermore, each of the inventions I-II and III has a distinctly different mode of operation, function or effect, such that there is no overlap between any of the groups. For example, the outcome or objective of screening for a modulator of cyclin-dependent kinase 9 activity is distinctly different from that achieved when such a compound is administered to a subject for the treatment of heart failure or cardiac hypertrophy, such that the execution of one method would not reasonably suggest the complete execution of any one or more of the other methods. For these reasons, the methods are considered to be independent and/or patentably distinct.

A telephone call was made to Melissa Acosta at Fulbright and Jaworski, L.L.P. on August 23, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

August 23, 2005

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